

REMARKS

This application has been reviewed in light of the Office Action dated October 31, 2005. Claims 41-47, 49-55, and 57-60 are pending in the application. Claims 41, 50 and 59 have been amended. No new matter has been added. Claims 48 and 56 are cancelled without prejudice. The Examiner's reconsideration of the rejection in view of the amendment and the following remarks is respectfully requested.

The present Office Action was received and is responsive to the claims submitted with an appeal brief on August 17, 2005. The Examiner stated that the unentered amendments submitted in the May 2005 response would overcome the prior art of record. By telephone the Examiner confirmed that the claims submitted in the May response were subjected to an additional search and would be allowable if resubmitted. The Examiner declined to do an Examiner's Amendment. The presently submitted claims are a resubmission of the claims in the May 2005 response. However, claims 48 and 56 have been cancelled without prejudice to further prosecution of the case.

By the Office Action, claims 48-56 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claims 48 and 56 have been cancelled without prejudice to further prosecution of the case.

By the Office Action, claims 41-60 stand rejected as being unpatentable in view of U.S. Patent No. 5,711,982 to Takemori et al. (Takemori).

The Examiner cites Takemori shows the use of the elements of the present claims in food products. However, the prior art fails to provide a gluten free and sugar free product

simultaneously as in the present claims. Claims 41, 50 and 59 have been amended to clarify that the composition is gluten-free. Gluten-free is now recited in the independent claims.

Takemori discloses a process for preparing a de-lactose milk having a fat and a protein which are homogenized. Its aim is to reduce lactose content. The finished product is a powdered form of milk or reconstituted form of milk. Once the de-lactose milk powder is produced, it may be employed in a chocolate with Xylitol and fiber to provide candy, not a cake or bread. Takemori does not disclose or suggest a gluten-free baked product as recited by the present claims. Instead, a biscuit or baked good disclosed by Takemori includes flour (gluten) for creating a dough (see e.g., col. 22, lines 40-52). One skilled in art would not arrive at the present invention based on Takemori.

As stated, Takemori mixes fat (lactose free milk fat) with protein to make an emulsion that can be sweetened with sugar alcohols and pulverized into a powder form. If the powder is employed to form dough, flour or other gluten containing substances are used. Takemori therefore fails to contemplate the benefits and the claims of the present invention.

Claim 59, recites, *inter alia*, a gluten-free baked product mix including a sugarless natural sweetening agent ...comprising xylitol, a whey protein in an amount between about 2 to about 40% by weight to support a structure of the food product produced using the food composition; and at least one of a fiber or a stabilizer, said fiber to provide water-binding capacity and to provide additional bulk without adding caloric value, wherein the mix provides a baked product having consistency and texture equivalent to conventional baked products without the use of gluten.

Gluten provides the bonding capability, stability and texture to a baked product. The prior art required gluten (flour) to provide these features in cakes and breads. The present invention provides the texture and stability without gluten. This is not taught or suggested by Takemori,

which actually teaches the use of flour in baked goods. Therefore, it is respectfully requested that the Examiner reconsider the rejection.

In addition, while the present invention employs ingredients, which may be known, however, the combination of these ingredients and proportions to form a gluten-free and sugar-free baked product having the stability, texture, taste and consistency of a conventional high fat product containing gluten (see e.g., Exhibit B (Fred Priedemann), paragraphs 5 and 6; Exhibit D; Exhibit E (Al Rosen), paragraph 8; and Exhibit H, paragraph 11) was and is not readily known to those skilled in the art (see e.g., Exhibit J paragraphs 4-7). The combination and proportion of the ingredients are not a mere optimization as the Examiner has contended, but a new, useful and unobvious result is obtained, which has been desired (see Exhibit 1 (Time Magazine Article), submitted previously) but not provided in the prior art (see Exhibit H).

While the present claims are believed to be in condition for allowance for at least the reasons stated, the declarations of commercial success and long-felt are believed to provide "a proper showing that further establishes a coaction or cooperative relationship between the selected ingredients which produces a, new, unexpected and useful function" of the present invention in accordance with *In re Benjamin D. White* 17 C.C.P.A. (Patents) 956, 39 F. 2d 974.

As stated, one new and useful function provided by the present invention is a dessert or food product that has the texture, stability and taste of a product that would otherwise have to include a fat and gluten, without the fat and gluten. This is an enormous benefit to those who suffer gluten intolerance and allergies (See e.g., Time Mag. Art. Exhibit 1, Exhibit F and Exhibit J).

It is therefore respectfully submitted that a proper showing of the coaction of the ingredients produces a new and useful function. Reconsideration is respectfully requested.

Furthermore, the present invention provides the product mix without fats as employed by Takemori. Takemori provides a useful method for reducing lactose from milk, but does so by employing lactose-free milk-fat. One skilled in the art looking at Takemori would not arrive at the present invention, which is moving away from the use of fat, sugar and gluten in a dessert or food product.

The Examiner has rejected the declarations submitted with the last office action stating that:

- 1) It is unclear that the product marketed is commensurate in scope with the claimed invention, and
- 2) It is unclear whether the consumer was free to choose on the basis of objective principals.

Specifically, the invention was heavily promoted in national best sellers.

Regarding item 1, in the declaration of Thomas Thornton at paragraphs 5 and 6, it is clearly stated that the mixes were blended in accordance with the claims of the present application. This is supported by the statements of Dr. Fran Gare (Exhibit H, paragraphs 14 (second one)). At the time of the signing, the claims were substantially the same as now presented. Therefore, the product mix is commensurate in scope with the claimed invention as attested to by the individuals that are best suited to state so. The product label (Exhibit A) demonstrates the ingredients list of the product (including Xylitol, whey protein, and fiber) that has experienced the commercial success as described in Thomas Thornton's declaration. Claims 41, 50 and 59 (and the dependents claims) recite these ingredients. Therefore, based on the product label, and the declarations, which provide statements that the product followed the claims, it is respectfully submitted that the product marketed was and is commensurate in scope with the claimed invention. Reconsideration of the rejection is earnestly solicited.

Regarding item 2, there is a statement in Dr. Pescatore's declaration that the book was a bestseller. However, upon information and belief, the book was published in the late spring (June

2004) time frame. The data on commercial success was provided for the period beginning in 2002 through May of 2004 ("ending June 1, 2004", see Thomas Thornton's declaration paragraph 12).

The book sales did not promote the product sales as the book was published too late to affect the data provided. The statements made by Dr. Pescatore is that the product mixes of the present invention met his high standards for health and were put in his latest book for that reason. The commercial success of the product mixes and the data provided in Mr. Thomas Thornton's declaration was provided for a time period before Dr. Pescatore's book was published.

As stated in Thomas Thornton's declaration paragraphs 10, 18, and 19, there was no advertising, and sales were based substantially on word of mouth. It is therefore submitted that consumers were free to choose this product over the thousands of products available on the market based on objective criteria and NOT based on high cost advertising or promotion programs.

In summary, the present claims provide a non-obvious combination of ingredients resulting in a product suitable for use with individuals who have gluten intolerance. The gluten-free product provided is a non-obvious result for which a long-standing need existed. The products commercial success provides support of its non-obviousness as does the failed attempts by one skilled to reproduce the mixture (see Exhibit J). The teachings of Takemori would not lead one skilled in the art to produce the present invention. Takemori solves a completely different problem in a completely different way.

It is therefore respectfully submitted that the present claims are in condition for allowance over the cited art. The present invention teaches a novel formulation that provides a gluten-free and sugar free all natural product that is both stable and tasty.

The Applicant would like to thank the Examiner for the telephonic interviews granted by the Examiner. The Examiner stated that the gluten-free aspect of the claims should be recited in the

body of the claim instead of the preamble and asked to specifically address items 1 and 2. The Examiner is invited to contact the undersigned to further discuss the case.

In view of the foregoing amendments and remarks, it is respectfully submitted that all the claims now pending in the application are in condition for allowance. Early and favorable reconsideration of the case is respectfully requested.

It is believed that no additional fees or charges are currently due. However, in the event that any additional fees or charges are required at this time in connection with the application, they may be charged to applicant's representatives Deposit Account No. 50-1433.

Respectfully submitted,

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